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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,339	06/02/2005	Mayumi Kotani	8156/84352	3456

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EXAMINER

CLARK, AMY LYNN

ART UNIT	PAPER NUMBER
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1655

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/537,339

Applicant(s)

KOTANI ET AL.

Examiner

Amy L. Clark

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-20, 22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/2/2005; 9/2/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group V, claim 21 in the reply filed on 16 October 2006 is acknowledged. The traversal is on the grounds that it is suggested that the art can be searched consistent with the claimed subject matter, Applicants caused in Information Disclosure Statement to be filed on June 2, 2005 and caused another Information Disclosure Statement to be filed on September 2, 2005 and that Applicants sought to discharge duty of candor obligations while concurrently reducing the search burden in view of the constructive guidance of M.P.E.P. Section 803 (all claims can and should be examined in one case when search burden is not undue).

This is not found persuasive because the inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I is drawn to a composition comprising a green-yellow vegetable and a light-colored vegetable, whereas Groups II-VII are drawn to various methods. Group I is drawn to a method of inhibiting the generation of blood lipid peroxides, which comprises ingesting effective amounts of a green-yellow vegetable and a light-colored vegetable, Group III is drawn to a method for lowering blood TBARS levels of suppressing an elevation of blood TBARS levels, which comprises ingesting effective amounts of a green-yellow vegetable and a light-colored vegetable, Group IV is drawn to a method of increasing blood vitamin E levels, which comprises ingesting effective amounts of a

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green-yellow vegetable and a light-colored vegetable, Group V is drawn to a method of enhancing blood antioxidant activity, which comprises ingesting effective amounts of a green-yellow vegetable and a light-colored vegetable, Group VI is drawn to a method for lowering blood active oxygen levels or suppressing an elevation of blood active oxygen levels, which comprises ingesting effective amounts of a green-yellow vegetable and a light-colored vegetable and Group VII is drawn to a method of preventing or treating diabetic complications, which comprises ingesting effective amounts of a green-yellow vegetable and a light-colored vegetable. A search for a composition comprising a green-yellow vegetable and a light-colored vegetable may be used as a skin care product or as a food and does not require the particulars of the methods of Groups II-VII.

Furthermore, Claim 1, at least, is anticipated by or obvious over Rosso et al. (Reference U*, The New Basics Cookbook, 1989) because Rosso teaches yellow pepper soup comprising yellow bell peppers, onions and leeks (See page 94), which reads on a composition comprising a green-yellow vegetable and a light-colored vegetable. Consequently, the special technical feature which links the claims does not provide a contribution over the prior art, so unity of the invention is lacking.

In response to Applicant's argument that Applicants caused an Information Disclosure Statement to be filed on June 2, 2005 and caused another Information Disclosure Statement to be filed on September 2, 2005 and that Applicants sought to discharge duty of candor obligations while concurrently reducing the search burden in view of the constructive guidance of M.P.E.P. Section 803 (all claims can and should be

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examined in one case when search burden is not undue), please note that while the Examiner appreciates Applicant's concern with easing the search burden on the Examiner, Applicant is reminded that in 371 applications, the inventions are restricted with respect to whether they relate to a single general inventive concept under PCT Rule 13.1 and whether under PCT Rule 13.2, they lack the same or corresponding special technical features. Since the inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons provided in the previous Office Action and for the reasons provided above. Please also note that MPEP 1893.03(d) states, "When making a lack of unity of invention requirement, the examiner must (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group. The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. See MPEP § 1850 for a detailed discussion of Unity of Invention. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at

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least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key." Therefore, Applicant's argument that the Applicants sought to discharge duty of candor obligations while concurrently reducing the search burden in view of the constructive guidance of M.P.E.P. Section 803 (all claims can and should be examined in one case when search burden is not undue), is moot since the election/restriction under PCT Rule 13.1 and PCT Rule 13.2 is based upon whether the inventions relate to a single general inventive concept under PCT Rule 13.1 and whether under PCT Rule 13.2, they lack the same or corresponding special technical features. Since there appears to be no contribution over the prior art, unity of the invention is, indeed, lacking.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 1-23 are currently pending.

Claims 1-20, 22 and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 16 October 2006.

Claim 21 is under examination.

Information Disclosure Statement

The information disclosure statements (IDS) were submitted on 2 June 2005 and 2 September 2005. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the invention as described in the specification. Figures 1-3 are completely ambiguous and very confusing due to the number of lines and the inadequate labeling. Is Applicant attempting to plot all people studied? If so, then Applicant needs to either calculate an average and plot that or find some way to plot the changes by either adding other figures, a table wherein Applicant writes down the measured changes in a numerical fashion, or finds a better way to plot the changes. As currently provided, and mentioned above, the Figures as currently drawn are completely ambiguous and do not appear to correlate to the description provided in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as

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"amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: A method of reducing blood TBARS levels, increasing blood vitamin E levels, and increasing TRAP levels in diabetic patients comprising (administering/ingesting) a vegetable beverage comprising broccoli puree, celery juice, lettuce juice, cabbage juice, spinach juice, parsley juice, komatsuna and Japanese radish leaf.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing blood TBARS levels of diabetic patients, increasing blood vitamin E levels in diabetic patients, and increasing TRAP levels in diabetic patients drinking a vegetable beverage comprising Broccoli puree (10%), Celery juice (15%), Lettuce juice (15%), Cabbage juice (20%), Spinach juice (10%), Parsley juice (5%), Komatsuna (1%) and Japanese radish leaf (1%) for two weeks, does not reasonably provide enablement for a method of enhancing blood antioxidant activity, which comprises ingesting effective amounts of a green-yellow vegetable and a light-colored vegetable because the method, as claimed, is incredibly broad and could refer to any type of antioxidant found in the blood and could refer to any type of green-yellow vegetable or any type of light-colored vegetable. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make any invention commensurate in scope with these claims.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Any composition of matter having a method of enhancing blood antioxidant activity critical or essential to the practice of the invention, but not included in the claims is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). In view of the breadth of the claims and the

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lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, Claim 21 is not considered to be fully enabled by the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 21 are rendered uncertain by the phrase "A method of enhancing blood antioxidant activity which comprises ingesting effective amounts of a green-yellow vegetable and a light-colored vegetable" because it is unclear as to what Applicant means by "green-yellow vegetable" and "light-colored vegetable". What specifically does Applicant mean by "green-yellow vegetable" and "light-colored vegetable"? The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Strain et al. (V, Euro. J. Clin. Nutr. 2000; 54: 828-833).

Strain teaches that the plasma carotenoids measured in men who consume four or more portions of fruit and vegetables, such as carrots, onions and greens, are significantly higher than those with lower fruit and vegetable consumption. Strain further teaches that each carotenoid showed a dose response relationship with fruit and vegetable consumption. Strain further teaches that the positive intake associate between fruit and vegetable intake and plasma carotenoids is consistent with results of a randomized controlled trial, where the intervention group was asked to consume eight servings of fruit and vegetables a day (See page 831, columns 1 and 2, and Tables 2 and 3, page 830), which reads on claim 21.

Therefore, the reference anticipates the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Amy L. Clark
March 25, 2007


MICHELE FLOOD
PRIMARY EXAMINER